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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,676	01/26/2004	Peter Rohnert	13183.0037	9441
26712	7590	03/05/2007		
HODGSON RUSS LLP ONE M & T PLAZA SUITE 2000 BUFFALO, NY 14203-2391			EXAMINER SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1625	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/764,676

Applicant(s)

ROHNERT ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12/4/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 45-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 45-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 45-86 are pending in this application.

Claims 1-44 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jablonka et al., Archivum Vetrinarium Polnicum, (1992), Vol. 32, pages 57-66; in view of Stoll et al., Annals N.Y. Acad. Sci. (1994), pages 122-128; Biewenga et al., Gen. Pharm., (1997), Vol. 29(3), pages 315-331; Sian et al., Annals of Neurology, (1994), Vol. 36(3), pg. 348-355; and Kozhevnikova et al., Bull. Experimental Biol. and Med. (1999), Vol. 128(11), pg. 535-537.

Applicant claims a composition comprising ambroxile and Angiotensin-converting enzyme inhibitor (ACE inhibitor) optionally, α -lipoic acid and method of use for treating neurodegenerative diseases. In preferred embodiment applicant claims several dosages, types of composition, and routes of administration.

Determination of the scope and content of the prior art (MPEP §2141.01)

Jablonka et al., teach a composition comprising ambroxile for stimulating the production of GSH. Stoll et al., teach a composition comprising α -lipoic acid for improving cognitive function such as, diabetic polyneuropathy, Alzheimer's and Parkinson's diseases and aging. Biewenga et al., teach a composition comprising α -lipoic acid as antioxidants in brain ischemia,

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stroke, diabetic polyneuropathy, Huntington and Parkinson's diseases. Biewenga et al., also teach that lipoic acid stimulates increased level of GSH in neuroblastoma, melanoma and human T-lymphocyte cells. Kozhevnikova et al., teach a composition comprising inhibitors ACE inhibitors for neuroprotective activities, e.g. enalapril and captopril in cerebral ischemia. Sian et al., teach reduced level of GSH in patents suffering from Parkinson's disease and neurodegenerative disorders.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Jablonka et al., Stoll et al., Biewenga et al., and Kozhevnikova et al., is that applicant claims a composition comprising one or more of ambroxile, ACE inhibitor(s) and α -lipoic acid instead of a composition comprising ambroxile by Jablonka et al., compositions comprising α -lipoic acid by Stoll et al., and Biewenga et al., and a composition comprising enalapril or captopril by Kozhevnikova et al. Applicant also claims several dosages, types of composition, routes of administration and treatment of neurodegenerative disorders.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

The compositions by the prior arts stimulate GSH level and Sian et al.; teach reduced level of GSH in patents suffering from Parkinson's disease and neurodegenerative disorders. The combination of the prior arts' composition for treating or preventing neurodegenerative disorders is prima facie obvious. "The idea of combining them flows logically from their having been individually taught in the prior art[s]" for stimulating GSH level, and that GSH level is low in neurodegenerative diseases. "Applicant's claim requires no more than mixing together the [individual] compositions." *In re Kerkhoven*, 205 USPQ 1069 (1980). See also, *In re Susi*, 169

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USPQ 423, 426 (CCPA, 197). "Assuming that [ambroxile, α -lipoic acid and ACE inhibitors] together produce an effect somewhat greater than sum of their separate effects . . . claim to their joint use is not patentable." *In re Crockett*, 126 USPQ 186 (CCPA, 1960). Therefore, the instant invention is prima facie obvious from the teachings of Jablonka et al., Stoll et al., Biewenga et al., Sian et al., and Kozhevnikova et al. Claiming dosages, types of composition, and routes of administration is not patentable significant because they do not rise to the level of invention under US patent practice.

Knowing that ambroxile, α -lipoic acid and ACE inhibitors, individually, stimulates GSH level and/or are useful for Parkinson's disease, neurodegenerative disorders and cerebral ischemia, one of ordinary skill in the art would have known to use them individually or combine them in a composition for the diseases. The motivation to combine them is from the teachings of the prior arts and from the common practice in medicine of using cocktail medication.

Applicant's arguments filed 12/4/06 have been fully considered but they are not persuasive. Applicant repeated the argument filed 5/30/06. Such is not persuasive for reasons set forth in the office action mailed 7/12/06. In response to the affidavit by Dr. Frank Striggow asserting synergistic effect of the instant composition. It is not persuasive because synergistic effect is enough for unobviousness where the result is "[r]eached by means of routine procedures as in the instant case.

Objection

Claims 64-81 are duplicates of 45-62 and must be deleted.

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Abstract

The abstract is still too long. Appropriate correction is required.

Drawing

The drawing submitted on 1/26/04 is objected to because hand written inscriptions on each page.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Thomas McKenzie, can be reached on (571) 272-0670. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1625

March 1, 2007